UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/302,863	04/30/1999	RAYMOND G. GOODWIN	2519	7568

22932 7590 01/02/2003

IMMUNEX CORPORATION
LAW DEPARTMENT
51 UNIVERSITY STREET
SEATTLE, WA 98101

EXAMINER
ROMEO, DAVID S

ART UNIT	PAPER NUMBER
1647	22

DATE MAILED: 01/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/302,863	GOODWIN ET AL.	
	Examiner	Art Unit	
	David S Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The request filed on September 25, 2002 (Paper No. 20) for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09302863 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 15-34 are pending and being examined. Any objection and/or rejection of record that is not maintained and/or repeated in this Office action is withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Citations by the examiner are in an alphanumeric format, such as "(a1)", wherein the "a" refers to the reference cited on the Notice of References Cited, PTO-892, and the "1" refers to the Paper No. to which the Notice of References Cited, PTO-892, is attached.

Maintained Formal Matters, Objections, and/or Rejections:

Claim Rejections - 35 USC § 112

Claims 15-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 or SEQ ID NO: 4, does not reasonably provide enablement for "TACI", "TACI-L", or a polypeptide encoded by a nucleic acid molecule 75% identical to SEQ ID NO: 1 or SEQ ID NO: 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are directed to or encompass "TACI" and "TACI-L" proteins. The specification teaches a polypeptide comprising the amino acid sequence of SEQ ID NO: 2 that binds a polypeptide comprising the amino acid sequence of SEQ ID NO: 4. The specification at page 5, lines 28-30, defines "TACI" by reference to WO 98/39361, and at page 6, lines 27-29, defines "TACI-L" by reference to WO 98/18921, EP 0869180A1 and WO 98/27114. WO 98/39361 (page 19, lines 12-18) defines TACI as a receptor protein having the amino acid sequence of as shown in SEQ ID NO: 2 or allelic variants, homologs, and analogs thereof. There are no structural limitations to the allelic variants, homologs, and analogs. WO 98/18921 (page 34, lines 23-25) defines Neutrokine-α (TACI-L) as including one or more amino acid substitutions, deletions or additions. There are no limitations on the number of amino acid substitutions, deletions or additions. The instant specification the instant specification does not identify those amino acid residues in the amino acid sequence of a TACI or a TACI-L which are essential for their biological activity and structural integrity and those residues which are either expendable or substitutable. In the absence of this information a practitioner would have to resort to a substantial amount of undue experimentation in the form of insertional, deletional and substitutional mutation analysis before they could even begin to rationally design a functional TACI or TACI-L having other than a natural amino acid sequence. Furthermore, there are no working examples of such allelic, homologous, or analogous polypeptides. Moreover, there is a lack of predictability in the art. Predicting structure, hence function, from primary amino acid sequence data is extremely complex and there doesn't exist an efficient algorithm for predicting the structure of a given protein from its amino acid sequence alone. See Bowie (u11) page 1306, column 1, full paragraph 1, and Ngo (v11) page 433, full paragraph 1, and page 492, full

paragraph 2. It is acknowledged that claims 29-34 recite SEQ ID NO: 2 or SEQ ID NO: 4, or some variant thereof, but the claims fail to link SEQ ID NO: 2 or SEQ ID NO: 4, or some variant thereof, with the recitation of "TACI" or "TACI-L". In view of the breadth of the claims, the limited amount of direction and working examples provided by the inventor, the unpredictability in the art and the quantity of experimentation needed to make or use the invention based on the content of the disclosure, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15-34 are recite the terms "TACI" and "TACI-L". Because the present specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "TACI" and "TACI-L" an artisan cannot determine what additional limitations are placed upon a claim by the presence of these terms. The metes and bounds of the claim(s) are not clearly set forth.

Claims 15, 29, 30 are indefinite over the recitation of "protein comprises ... fragments" because it is unclear if the protein comprises continuous or discontinuous "fragments". The metes and bounds of the claim(s) are not clearly set forth. It is suggested that the claims recite "a fragment".

Claims 33, 34 recite the limitation "the fragment of the polypeptide". There is insufficient antecedent basis for this limitation in the claim. There is sufficient antecedent basis for the limitation "the fragments of the polypeptide".

Claim Rejections - 35 USC § 103

Claims 15, 19, 20, 23, 25, 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chaudhary (6, cited by Applicants) in view of Bringman (a11) and Bram (13, cited by Applicants).

Chaudhary teaches human TNRL1-α having an amino acid sequence that is identical to TACI-L, SEQ ID NO: 4, of the instant invention (page 117, line 10, through page 118, line 2; Figure 11A), soluble forms thereof (page 34, lines 14-32), and humanized antibodies thereto (page 59, line 25). BJAB cells, a human B cell line, were treated with TNRL1-α and their survival was significantly reduced (page 118, lines 4-16). It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention that BJAB cells express a receptor for TNRL1-α (paragraph bridging pages 32-33). Bram (13, cited by Applicants) teaches the amino acid sequence of a human transmembrane lymphocyte receptor (TACI) (Figure 2) that is normally present in all B-cells (paragraph bridging pages 3-4). The amino acid sequence of TACI is 100% identical to Applicants' SEQ ID NO: 2. It is further noted that BJAB is a human B cell line. BJAB cells comprise a polypeptide that comprises an amino acid sequence selected from the group consisting of the amino acid sequence of SEQ ID NO: 2, the amino acid sequence of a fragment of SEQ ID NO: 2 wherein said fragment binds TACI-L, the amino acid sequence of a polypeptide encoded by a nucleic acid molecule that is at least 75% identical to SEQ ID NO:

1, and the amino acid sequence of amino acids 1-166 of SEQ ID NO: 2, absent evidence to the contrary. The BJAB cell receptor for TNRL1-α is a "TACI", absent evidence to the contrary. Treating BJAB cells with TNRL1-α and assaying for cell survival, as taught by Chaudhary, is a method comprising forming a composition comprising a TACI protein and a TACI-L protein and assaying for the level of interaction of the TACI protein and the TACI-L protein, wherein the interaction of TACI and TACI-L is identified. Chaudhary does not teach treating BJAB cells with TNRL1-α in the presence of a test compound, assaying for cell survival, wherein said compound affects the interaction of TACI and TACI-L.

Bringman teaches that the characterization and purification of lymphotoxin would be facilitated by antibody raised against the lymphotoxin active or receptor binding site or an adjacent region that neutralizes the cytotoxic activity of lymphotoxin (column 2, lines 22-26). A method is provided therein for obtaining lymphotoxin neutralizing antibody (paragraph bridging columns 7-8). Bringman does not teach treating BJAB cells with TNRL1-α in the presence of a test compound, assaying for cell survival, wherein said compound affects the interaction of TACI and TACI-L. However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to treat BJAB cells with TNRL1-α and assay for cell survival, as taught by Chaudhary, and to make a neutralizing antibody, as taught by Bringman, against TNRL1-α and to test that antibody for neutralization of TNRL1-α bioactivity in the BJAB cell survival assay, as taught by Chaudhary, with a reasonable expectation of success. Treating BJAB cells with TNRL1-α in the presence of an anti-TNRL1-α neutralizing antibody, and assaying for cell survival, wherein said antibody neutralizes the bioactivity of TNRL1-α identifies that antibody as a compound that affects the interaction of TACI and TACI-L. One of

ordinary skill in the art would be motivated to make this modification because antibody raised against a TNRL1-α active or receptor binding site or an adjacent region that neutralizes the cytotoxic activity of TNRL1-α would facilitate characterization and purification of TNRL1-α.

The invention is prima facie obvious over the prior art.

5

Specification

The amendment filed 03/19/2001 (Paper No. 14) is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not 10 supported by the original disclosure is as follows: The paragraph at page 5, line 28; the paragraph at page 5, line 31; the paragraph at page 6, line 27. Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found. See MPEP 608.01(p). The application as filed does not direct particular attention to specific portions of the referenced document where the subject matter 15 being incorporated may be found.

Applicant is required to cancel the new matter in the reply to this Office action.

Conclusion

No claims are allowable.

20

This is a continuation of applicant's earlier Application No. 09302863. All claims are drawn to the same invention claimed in the earlier application and could have been finally

rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306
AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
DECEMBER 18, 2002